

REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Claims 3, 5, and 6 have been canceled. Applicants wish to thank Examiner Lankford for the teleconference conducted on Wednesday, September 3, 2003. As per the discussion, claim 1 has been amended to incorporate limitations from claims 3 and 5 and to further specify that the magnetic or magnetizable element can be external to the culture vessel. Applicants submit that support for the amendment can be found, for example, at page 48, lines 17-26, or in Example I, at page 58, lines 9-18. Claim 8 has been amended for clarity and new claim 18 has been added. Support for new claim 18 can be found throughout the specification, in particular in originally filed claims 1 and 6. No new matter has been added. Following the amendments, claims 1, 2, 4, and 7-18 are pending in the application. These amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

***Rejections under 35 U.S.C. § 112, second paragraph (indefiniteness)***

Claims 1-17 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. In particular, the Action contends that claim 1 is confusing in the phrase "or a magnetizable element" is not included with "said magnet" when the positioning is mentioned. The Action further contends that there is no antecedent basis for "magnetic in claim 2. Finally, the Action alleges that claim 8 is indefinite because the preamble calls for aggregation but there is no positive recitation of this step.

Applicants have amended claim 1 to recite "wherein said magnet or magnetizable element is positioned...". Applicants have amended claim 2 to change "magnetic" to "magnet". Lastly, Applicants have amended claim 8 to include positive recitation of aggregation. Applicants submit that these amendments obviate the rejection and respectfully request its withdrawal.

***Rejections under 35 U.S.C. § 102(b)***

Claims 1-4 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Jones *et al.* (U.S. Patent No. 5,672,505) and Bruno *et al.* (U.S. Patent No. 5,972,721). In particular, the Action alleges that Jones *et al.* teaches a cell culture device which incorporates a magnet to attract beads. The Action further alleges that Bruno *et al.* teaches a cell culture device which incorporates a magnet to attract immuno-specific beads. Accordingly, the Action contends that these references anticipate the claimed subject matter.

Applicants respectfully traverse the rejections on the following grounds.

Applicants note that the claims have been amended without prejudice or acquiescence, to recite wherein said magnet or magnetizable element is positioned within a wall of or external to said culture vessel, and new claim 18 has been added with the recitation that said magnet or magnetizable element is not positioned within the culture vessel. Applicants submit that support for this amendment can be found in specification as filed, in particular, in Example I, at page 58, lines 9-18, and claim 6 as originally filed (now canceled). As for descriptive support for the negative proviso in newly added claim 18, Applicants wish to direct the Examiner's attention to *In re Johnson*, 194 U.S.P.Q. 187 (CCPA 1977). In that case, the applicant had claimed a genus relating to certain thermoplastic polymers and, during prosecution, had amended the claims to exclude several known prior art species that fell within the claim genus. The court found that claiming the genus, less the known prior art species, satisfied the written description requirement of 35 U.S.C. §112, first paragraph.

Applicants submit that the cited references do not teach or suggest each and every element of the claimed invention. In particular, Jones *et al.* teaches a suspending arm, having an element for holding at least one specimen, that is adapted to insert into a standard culture flask wherein, when inserted into the flask, the holder is suspended within the bottle. Nowhere does Jones *et al.* teach or suggest a magnet or magnetizable element positioned within the wall of the culture vessel or external to said culture vessel, or wherein said magnet or magnetizable element is not positioned within the culture vessel, as recited in the claims as amended and new claim 18. Furthermore, Applicants submit that Jones *et al.* could not have appreciated that it is particularly advantageous to use a magnet while culturing cells, as is disclosed by Applicants (see for

example, Example I, pages 56-64). On the contrary, Jones *et al.* merely lists a magnet as one of a litany of embodiments of the described specimen, and particularly describes the use of a magnet "for conducting affinity separations" (see Column 4, lines 21-25). Nowhere does Jones *et al.* describe simultaneous stimulation and magnetic concentration of cells as taught in the instant application. Bruno *et al.* merely describes an apparatus for immunomagnetic separation and concentration of target biological materials. Contrary to the assertion of the Action, nowhere does this reference teach or suggest an apparatus adapted for the culture of human cells. Accordingly, Applicants submit that neither Jones *et al.* nor Bruno *et al.* anticipates the currently claimed invention. Withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

***Rejections under 35 U.S.C. § 103(a)***

Claims 1-17 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Fodstad *et al.* (U.S. Patent No. 6,184,043) and Bruno *et al.* Specifically, the Action contends that both references teach attaching antibodies to magnetic beads and then binding said immunospecific beads to a target. Further, the references allegedly teach that the targets are aggregated using a magnetic field following binding. Accordingly, the Action concludes that the claimed invention was *prima facie* obvious to the skilled artisan at the time the invention was made.

Applicants respectfully traverse the rejection and submit that the combined primary and secondary references, taken for what they teach as a whole, do not teach or suggest the claimed invention. Therefore, Applicants submit that the claimed invention would not have been obvious to the ordinarily skilled artisan at the time of filing.

Specifically, to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (CCPA 1974). As noted above in the context of the rejection under 35 U.S.C. § 102(b), Bruno *et al.* merely describes an apparatus for immunomagnetic separation and concentration of target biological materials. Nowhere does this reference teach or suggest an apparatus adapted for the culture of human cells. The teachings of Fodstad *et al.* do not overcome the deficiencies of Bruno *et al.* In particular, Fodstad *et al.* only describes methods of immunomagnetic coating of

a target cell followed by observation of complexes under a conventional microscope. This reference does not teach or even suggest an apparatus adapted for the culture of cells. Accordingly, Applicants submit that the claimed invention is not obvious in view of the cited references, either alone or in combination. Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a).

The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that the claims remaining in the application are now believed to be in condition for allowance. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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